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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,451	01/27/2004	Craig A. Townsend	62732.000152	8691

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EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,451	TOWNSEND ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-31 and 33-48* is/are pending in the application.

4a) Of the above claim(s) *25-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30, 31 and 33-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed November 22, 2005 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 25-48 were pending. Applicants canceled claim 32 and amended claim 30, 44 and 45. No claims were added. Therefore, claims 25-31 and 33-48 are currently pending and examined on the merits.

4. Claims 25-29 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim.

5. Therefore, claims 30, 31 and 33-48 are examined on the merits in this action.

6. Please note: This application contains claims 25-29 drawn to a nonelected invention. This was addressed in the previous action (see Non-final Rejection, paragraph 3). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Withdrawn Objections/Rejections

7. The 35 U.S.C. § 112, first paragraph rejection has been withdrawn in part (see below).

Outstanding Objections and/or Rejections

Claim Rejections - 35 USC § 112, first paragraph

8. Claims 30, 31 and 33-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds that inhibit a narrow range of mycobacterium including *tuberculosis*, *bovis* and *avium-intracellulare*, does not reasonably provide enablement for the treatment of "any" mycobacterial infection using the full scope of the claimed compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". Some of these factors may include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the level of one of ordinary skill;
(5) the level of predictability in the art;
(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and

(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claims are broad because they include the treatment of "any" microbial-based infection in "any" animal, which would encompass a large number of unrelated etiologies. Consequently, the nature of the invention cannot be fully determined because the invention has not been defined with particularity.

(3 and 5) The state of the prior art and the level of predictability in the art: The prior art indicates that Applicants' claimed compounds can only be used to inhibit a very narrow range of mycobacterial species including *tuberculosis*, *bovis* and *avium-intracellulare* (e.g., see Jones, P. B.; Parrish, N. M.; Houston, T. A.; Stapon, A.; Bansal, N. P.; Dick J. D.; Townsend, C. A. "A New Class of Antituberculosis Agents" *J. Med. Chem.* **2000**, *43*, 3304-3314, page 3308, column 1, last full paragraph, "The compounds marked with an asterisk in Table 1 [i.e., Applicants' claimed compounds] were also tested against other bacterial strains including *Staphylococcus aureus* (ATC 29213), *Enterococcus faecalis* (ATCC 29212), *Escherichia coli* (ATCC 25922), and *Pseudomonas aeruginosa* (ATCC 27853). ***None exhibited any activity against these bacteria***"; see also page 3309, column 1, paragraph 1, "... these compounds are highly species-specific [i.e., Applicants' claimed compounds], showing no activity against other bacteria including strains of nonpathogentic mycobacteria, such as *M. smegmatis* [i.e., no activity even for other closely related mycobacteria"; see also Table 1 in specification).

(4) The level of one of ordinary skill: The level of skill required would be high, most likely at the Ph.D. level.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants provide only a narrow ranges of examples where their claimed compounds are used to treat *tuberculosis*, *bovis* and *avium-intracellulare* (e.g., see specification, Table 1 wherein only MTB, BCG and MAI are disclosed).

(8) The quantity of experimentation needed to make or use the invention base on the content of the disclosure: As a result of the broad and unpredictable nature of the invention and the lack of specific guidance from the specification, the Examiner contends that the quantity of experimentation needed to make and or use the invention would be great. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 * n.23 (Fed. Cir. 19991). In this case, Applicants have not provided any working examples that would teach this enormous genus that falls within a highly unpredictable art area. Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Response

9. Applicant's arguments directed to the above Enablement rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "Applicants have amended claim 30 to ... Z = $-CH_2-$, $-CH_2CH_2-$,-NH-, and -CH=CH-. the Examiner has already indicated that the specification enables compounds wherein Z = $-CH_2-$ or -CH=CH- ... Compounds 13 and 28-31 in Table 1 of Jones et al. disclose [that] ... $-CH_2CH_2-$ and –NH- [are also enabled]" and cite Table 1 of Jones et al. in support of this position (e.g., see 11/22/05 Response, page 6, last paragraph).

[2] Applicants argue, "... the claims [have been amended] to limit 'microbial based infections' to 'mycobacterial infections.' Applicants respectfully submit that the specification enables the treatment of mycobacterial infections with the claimed compound by demonstration of the effect of numerous homologous compound on numerous different Mycobacterium sp." (e.g., see 11/22/05 Response, page 7, paragraph 1).

This is not found persuasive for the following reasons:

[1] The Examiner finds Applicants' arguments on this issue persuasive and, as a result, the above rejection has been amended from its original version to reflect these concerns.

[2] The Examiner respectfully disagrees. Jones et al. states, "... these compounds are highly species-specific [i.e., refers to Applicants' claimed compounds], showing no activity against other bacteria including strains of nonpathogenic mycobacteria, such as *M. smegmatis* [i.e., no activity even for other closely related mycobacteria" (e.g., see page 3309, column 1,

paragraph 1; compare to Table 1 in specification). Thus, Applicants' assertion that "numerous different Mycobacterium" can be used is not supported in fact. Table 1 of the specification only shows utility for MTB, BCG and MAI. Consequently, Applicants are not enabled for the broader genus of "mycobacterial infections."

Accordingly, the Enablement rejection cited above is hereby maintained.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
February 7, 2006

ANDREW WANG
SUPERVISORY PATENT EXAMINER
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